REMARKS

Claims 1-25 are currently pending in the application. Claims 1, 17, 22, and 23 are in independent form. New claims 26-28 have been added and are based on original claims 2-4. No new matter has been added.

Claims 19-21 and 24-25 stand objected to under 37 CFR §1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claims. In response thereto, Applicant has amended claim 17 to remove multiple dependencies. Applicant notes that claim 25 is only a dependent claim depending on a multiple dependent claim. Reconsideration of the objection is respectfully requested.

Claims 1-5 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,951,539 to Nita. Specifically, the Office Action holds that Nita discloses a neurosurgical catheter with an external diameter not more than 0.5 mm. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Nita, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

Nita discloses an intravascular catheter; see column 1, lines 15-16 and 53-55. The catheter is inserted into the vasculature (e.g. in the groin region) and can be guided through arteries to the brain; see column 2, lines 1-6. The end of the catheter disclosed in Nita is thin. The term "Mils" used in Nita is an imperial measurement of length (i.e. one thousandth of an inch) and this should not be confused with metric millimeters (mm). 1 Mil thus equals around 0.0255 mm and the "10 Mils" wall thickness of tubular member 206 is thus only 0.255 mm. The catheter tip of Nita can be between 1.5 and 5 French as described at lines 10-11 of column 17. This refers to the outer diameter of the catheter. The French scale can be converted to millimeters by dividing by three. A catheter of 1.5 French thus has a diameter of (by definition) 0.5 mm.

Claim 1 of the present invention is limited to a neurosurgical catheter comprising a fine tube for insertion into the brain parenchyma. As would be understood by one skilled in the art, the brain parenchyma is the functional part of the brain (i.e. the brain tissue containing neurons, etc.) and insertion of an object into the brain parenchyma thus inherently means passing that object directly through the tissue of the brain. This well understood meaning of the term brain parenchyma is also clearly evident from the description of the present specification where direct insertion of catheters and other instruments into the brain tissue through holes formed in the skull of the patient is described; e.g. see figure 11 which shows a catheter passing through the skull and into the brain parenchyma. New claim 26 is also limited to a neurosurgical catheter comprising a fine tube for insertion into the brain parenchyma.

Nita does not disclose a neurosurgical catheter comprising a fine tube for insertion into the brain parenchyma but instead describes an intravascular catheter that

is inserted into the vasculature and guided through the arteries to blood vessels in the brain. At no time is the catheter in Nita inserted into the brain parenchyma.

Nita relates to a different technical field (intravascular catheters) than the present invention. There is also no suggestion in Nita about using an intravascular catheter for direct insertion into the brain parenchyma and the Nita catheters would simply be unsuitable for such a function. The present invention is also thus unobvious in view of Nita.

Applicant has amended claim 1 to require a stop surface on the catheter. This stop surface allows the depth of insertion of the catheter into the brain parenchyma to be precisely defined and is considered to be critical to ensuring that catheters can be inserted so as to accurately reach the desired target in the brain. The stop surface is described in the specification at paragraphs [0013], [0015], [0041], [0045], and [0059]. Nita does not disclose a stop surface on the catheter as required by presently amended claim 1.

Therefore, since Nita does not disclose a neurosurgical catheter that is inserted into the brain parenchyma and includes a stop surface as set forth in the presently pending independent claims, the claims are patentable over Nita and reconsideration of the rejection is respectfully requested.

Claims 1, 5-18, and 22-23 stand rejected under 35 U.S.C. § 102(e), as being anticipated by U.S. Patent No. 6,902,569 to Parmer. Specifically, the Office Action holds that Parmer discloses a neurosurgical catheter, a dome shaped hub with flanges that allow bone screws to be inserted and connected to a guide tube as well as a method of using the device. Reconsideration of the rejection under 35 U.S.C. § 102(e), as anticipated by Nita, as applied to the claims, is respectfully requested.

Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

Parmer discloses a catheter that can be inserted directly into the brain parenchyma. The smallest outer diameter catheters disclosed in Parmer are 3 French (i.e. 1 mm); see lines 13-17 of column 15. In particular, Parmer discloses a guide device (e.g. see figure 3; column 9, line 39 to column 10, line 32) that includes a base 210 that is attached to a hole formed in the skull, a moveable member 220 (e.g. a ball with a channel through it), an elongate guide stem 240 and a locking member 230. The moveable member is aligned using positioning stem 400 shown in figure 3 and is then locked in place by the locking member 230. Once locked, an instrument can be guided to the required target (column 13, lines 49-50). As shown in figure 8 (see also column 13, line 51 to column 14, line 20), the upper parts of the guide device may be removed over an inserted flexible instrument 229 (e.g. a catheter). This leaves the flexible instrument 229 and base 210 as shown in figure 8a. A cap 310 can then be used to engage the base 210 and hold the flexible instrument in place. Such a cap is shown in figure 9 (see column 14, lines 22-37). The proximal end of the flexible instrument (i.e. the part protruding from the skull) can then be tunneled subcutaneously. The catheters disclosed in Parmer are merely flexible plastic tubes. The tubes are held in place using a clip-on cap that is introduced after insertion. Parmer does not disclose a catheter including a stop surface, and therefore, Parmer does not anticipate claim 1.

Regarding claim 22, there is no disclosure in Parmer of a neurosurgical guide device as recited in claim 22. Parmer does disclose a guide stem 240 (e.g. figure 1) for use in guiding instruments to a target in the brain, but this guide stem is external i.e. it remains outside of the skull). Parmer does not disclose a guide device having a tube for insertion into the brain of a patient. As stated above, Parmer does

disclose the insertion of flexible instruments (e.g. catheters) into the brain. However, such a catheter is not a neurosurgical guide device. In addition, the catheters disclosed in Parmer are lengths of tubing having an external diameter of 1 mm or more. A base 210 and cap 310 can be provided to secure such tubes in place after insertion, but there is no disclosure of providing a tube for insertion into the brain having a head at its proximal end for attachment to the skull of a patient, i.e. the head being attached to the tube before insertion. Claim 22 is thus not anticipated by Parmer.

Regarding claim 23, Parmer does not disclose a guide tube as defined in claim 23. In addition, there is no disclosure in Parmer of the steps of inserting a tube into the brain and then securing a head of that tube to the skull. In Parmer, the base 210 is secured to the skull before anything is inserted into the brain. Parmer also fails to disclose the feature of inserting the distal end of a tube to fall short of a target by between 5 and 20 mm. Also, there is no disclosure in Parmer of inserting a catheter through a tube that is already inserted in the brain. Therefore, since none of the required steps of claim 23 are disclosed by Parmer, claim 23 is not anticipated by Parmer.

Regarding new claim 26, Parmer does not disclose a catheter having an external diameter of 0.7 mm or less. Claim 26 is therefore not anticipated by Parmer.

Neither is the present invention obvious over Parmer. Parmer discloses a particular arrangement for inserting catheters into the brain parenchyma. There are no teachings in Parmer related to providing a catheter having a stop surface as per claim 1 of the present invention, and certainly no mention of how such a surface can be used (e.g. with a guide tube) to very accurately define catheter insertion depth.

Similarly, Parmer mentions catheters having an external diameter of 1 mm or greater. There are no teachings in Parmer that catheters having an external diameter of 0.7 mm or less could be provided and certainly no mention of the advantages of such fine catheters that are outlined in paragraph [0061] of the present invention. If anything, Parmer would appear to teach that smaller diameter catheters could not be used because of the lack of guidance of such catheters within the brain. The use of catheters having an external diameter of no more than 0.7 mm optionally in combination with an intraparenchymal guide device (e.g. as defined in claim 22) is particularly advantageous. This is in no way obvious from Parmer.

Therefore, since Parmer does not disclose a catheter having a stop surface, a neurosurgical guide device, inserting a tube into the brain, or a catheter having an external diameter of 0.7 mm or less, as set forth in the presently pending independent claims, the claims are patentable over Parmer and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Dated: 2/2/09

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Terry Horst